Section II. (Remarks)

Pending Claims

Claims 1-36 are pending.

Allowable Claims

The Office Action indicates that claims 3, 4, 7, 11, 12, 22, 23, 26, and 30 are allowable. Applicants thank the Examiner for such indication.

Claims Rejected

The Final Office Action indicates on the Office Action Summary page that claims 1-2, 5-6, 8-10, 13-21, 24-25, 27-29, and 31-36 are rejected. However, the substance of the Final Office Action does not specify any grounds of rejection for the rejection of claim 13.

Accordingly, Applicants respectfully request that prosecution on the merits be re-opened so that Applicants have a proper opportunity to address this deficiency. In the alternative, Applicants respectfully submit that claim 13 is allowable and respectfully request an indication of allowance of claim 13.

Rejection of Claims 1, 5-6, 10, 15-20, 24-25, 29, 31 and 33-36 under 35 USC § 102(e)

The above-noted claims are rejected under 25 USC § 102(e) as being anticipated by Puri et al. (US 2004/0115818; hereinafter "Puri") for the reasons noted at pages 3-5 of the Office Action. This rejection is respectfully traversed for the reasons noted below.

In particular, in at least two places the Final Office Action asserts that:

> It appears as if applicant is relying upon the manner in which the film is applied as the patentable invention. Applying films in such a manner is previously . . . well known as illustrated by US Patents 4,786,561 [Fong I] and 4,690,865 [Fong II] (see paragraph 28 of applicants[']) specification). [(Final Office Action at page 2, paragraph 1, lines 12-15 and at page 4, lines 18-21; emphasis added.)]

In response, Applicants respectfully submit that the foregoing assertion mis-states Applicants' pending claims. Applicants are not relying upon the manner in which the film is applied in support of their contention that their claims are patentable. To the contrary, Applicants are relying on the expressly recited feature that "at least a portion thereof [i.e., of the vessel is in fact] shrink-wrapped in a film in a compressive state." There is no "as if" character to the above-noted expressly recited language appearing in Applicants' rejected claims.

The feature that the dispensing vessel has a portion thereof "shrink-wrapped in a film in a compressive state" is a positively recited feature of the relevant claimed invention. That feature has nothing to do with how it is prepared as claim 1 is not a method claim. Since claim 1 is directed to an "apparatus," the language "shrink-wrapped in a film in a compressive state" is a structural feature of the claimed apparatus of claim 1 (and that of all claims ultimately depending therefrom including claims 2, 5-6, 10, and 15-18).

With regard to "method" claim 19 (and that of all claims ultimately depending therefrom including claims 20, 24-25, 29, 31, and 33-36), claim 19 recites the positive step of "shrink-wrapping at least a portion of said vessel in a film . . ." as indicated in the rest of the entire claim. Here, the "shrink-wrapping" step is a claim requirement where the act of "shrink-wrapping" is one novel feature of the method claims – and, as such, the "manner in which the film is applied" is, in fact, at least a "patentable distinction."

In contrast, notably, the Puri reference states (in relevant part) that:

> Example 2
>
> A continuous thin layer of the slurry in Example 1 [hydrocarotene] is coated on the surface of the fluid storage vessel, such that a continuous layer of the reactive chemical material is left on the surfaces. A single layer or multiple layers of the slurry is placed on the surfaces. The chemical layer is then sealed by coating over it a continuous layer of a semi-permeable or microporous polymeric non-polymeric material which has characteristics such that it does not permit the atmospheric gases to permeate into the chemical material layer, ... [(See the Puri reference at col. 4, lines 20-31; emphasis added.)]

In view of the foregoing, the Puri reference discusses applying coating(s) of slurry followed by applying coating(s) of semi-permeable or microporous material. The Puri reference does not teach, disclose or suggest a "shrink-wrapped" apparatus as recited in Applicants' rejected claims. Nor does the Puri reference teach the step of "shrink wrapping" as required by Applicants' rejected method claims.

Thus, the Puri reference does not anticipate the above-noted claims rejected under 35 USC § 102(e) because the Puri reference fails to teach or disclose an expressly recited feature or step of the rejected claims i.e., a shrink-wrapped vessel (as recited) or a step of shrink-wrapping (also as recited).

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 5-6, 10, 15-20, 24-25, 29, 31, and 33-36 under 35 USC § 102(e).

Rejection of Claims 1, 5-6, 10, 15-20, 24-25, 29, 31 and 33-36 under 35 USC § 103(a)

The above-noted claims are rejected under 35 USC § 103(a) as being obvious over the disclosure of the Puri reference for the reasons noted at pages 3-5 of the Office Action. Applicants respectfully traverse this rejection for the reasons noted below.

Particularly, Applicants' foregoing comments and remarks regarding the deficiencies of the Puri reference in relation to the anticipation rejection under 35 USC § 102(e) are equally applicable to the present obviousness rejection under 35 USC § 103(a) over the disclosure of the Puri reference. As such, Applicants' foregoing comments and remarks regarding the Puri reference are incorporated herein by reference here without having to repeat the same.

In short, as noted, the Puri reference does not mention a "shrink-wrapped" apparatus. Also, the Puri reference does not mention the step of "shrink-wrapping." Therefore, the Puri reference does not disclose, teach or otherwise suggest the invention in Applicants' foregoing rejected claims reciting the "shrink-wrapped" feature or the method recital of the step of "shrink-wrapping" itself. Thus, the Puri reference does not make obvious Applicants' rejected claims.

At page 4 (penultimate line) of the Office Action, two U.S. patents, namely, 4,786,561 and 4,690,865 are cited for the proposition that these patents render it obvious to "shrink-wrap" a "fluid storage and dispensing apparatus" which is certainly not true. The above-noted '561 and '865 patents are discussed in paragraph [0028] of Applicants' specification. Applicants' specification teaches the use of the "shrink-wrapped" feature and the use of "shrink-wrapping" of a "fluid storage and dispensing apparatus" in conjunction with a "colorimetric member." See Applicants' specification originally filed. The suggestion to combine these features is not disclosed in the '561 or '865 patents absent the disclosure of Applicants' own specification. To suggest otherwise is to engage in the hindsight reconstruction of Applicants' own specification against them as a basis making an obviousness rejection. Such hindsight reconstruction has been consistently prohibited by the decisions of the Court of Appeals for the Federal Circuit.

In view of the foregoing comments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 5-6, 10, 15-20, 24-25, 29, 31 and 33-36 under 35 USC § 103(a) over the disclosure of the Puri reference.

Rejection of Claims 1, 5-6, 10, 16-20, 25, 29, 31 and 34-36 under 35 USC § 102(b)

The above-noted claims are rejected under 35 USC § 102(b) as being anticipated over the disclosure of U.S. Patent No. 6,093,572 (hereinafter "Stenholm") for the reasons noted at

pages 5-7 of the Office Action. This rejection is respectfully traversed for the reasons noted below.

The Office Action again asserts the statement noted above that:

> It appears as if applicant is relying upon the manner in which the film is applied as the patentable invention. Applying films in such a manner is previously . . . well known as illustrated by US Patents 4,786,561 [Fong I] and 4,690,865 [Fong II] (see paragraph 28 of applicants['] specification). [(Final Office Action at page 2, paragraph 1, lines 12-15, at page 4, lines 18-21, and at page 7, lines 9-12; emphasis added.)]

Once more, the same deficiencies noted above with the foregoing statement are equally applicable here and are incorporated herein without having to repeat the same.

Further, Applicants claims 1 (and claims ultimately depending therefrom) recite detection of "fluid leaking from the vessel" as opposed to something (e.g., oxygen) leaking into the vessel. This distinction is important because Stenholm is directed to a vessel for carrying pharmaceuticals and detecting leakage of oxygen into the vessel – which is exactly the opposite of what is recited in Applicants' claims.

In particular, Stenholm recites (in relevant part) that:

> The inventive indicators enable improvements related to the production of containers for storing oxygen sensitive pharmaceuticals and other sensitive products. [(Stenholm at col. 1, lines 16-19; emphasis added.)]
>
> * * *
>
> This container consists of an inner container, having one or several compartments for storage of drugs which readily can be mixed, just prior to administration, enclosed in a substantially airtight outer envelope. In the space between the inner container and the [outer] envelope, an oxygen scavenging composition is placed to consume residual oxygen and small amounts of oxygen penetrating through the [outer] envelope. To improve on the safety of the product, an oxygen indicator can be placed between the [outer] envelope and the inner container through which the transparent [outer] envelope visually indicates an oxygen leakage by a change in color. [(Stenholm at col. 1, lines 46-57; emphasis added.)]

Reference is also made to FIG. 6 of Stenholm reproduced below:

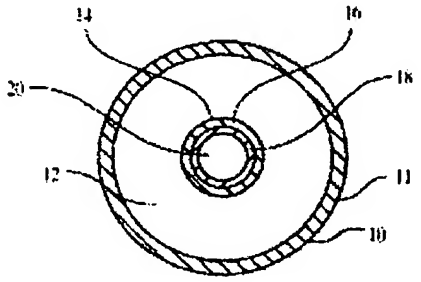

FIG. 6

FIG. 6 of Stenholm (reproduced above) depicts the outer envelope which is defined by "flexible transparent wall **11**" containing "oxygen-depleted solution or suspension of oxygen sensitive material **12**". The container of FIG. 6 also has in its interior an "indicator sachet **14**" having an "outer sachet wall **16**" and "inner sachet wall **14**" containing therein oxygen "indicator composition **20**". In view of the foregoing structure in FIG. 6 of Stenholm, it is indisputable that composition **20** detects the leakage of oxygen into the container from outside; whereas, in stark contrast, Applicants' claimed invention provides a "colorimetric member effective in exposure to fluid leaking from the vessel." See language recited in Applicants' independent claims 1 and 19.

The foregoing quotes and FIG. 6 of Stenholm taken together indicate that the disclosure of Stenholm refers to detecting oxygen leakage into the pharmaceutical container. By comparison, Applicants' claimed invention is directed to detecting leakage of fluid from the relevant container.

Also, Stenholm does not disclose, teach or suggest the "shrink-wrap" feature or "shrink-wrapping" step recited in Applicants' rejected claims. For all of the foregoing reasons, Applicants submit that the Stenholm reference fails to anticipate Applicants' claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the foregoing claims under 35 USC § 102(b) as being anticipated by Stenholm.

Rejection of Claims 1, 5-6, 10, 16-20, 25, 29, 31 and 34-36 under 35 USC § 103(a)

The foregoing claims are rejected under 35 USC § 103(a) as being obvious over Stenholm for the reasons noted at pages 5-7 of the Office Action. Applicants respectfully traverse this rejection for the reasons noted herein.

Applicants' foregoing comments and remarks regarding the Stenholm reference in relation to 35 USC § 102(b) are equally applicable to the instant rejection under 35 USC § 103(a). Because the Stenholm reference does not disclose, teach or suggest "a colorimetric member effective in exposure to fluid leaking from the vessel," the Stenholm reference fails to render obvious Applicants' claimed invention of claims 1, 5-6, 10, 16-20, 25, 29, 31 and 34-36 under 35 USC § 103(a).

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of the foregoing claims under 35 USC § 103(a) over the disclosure of the Stenholm reference.

Rejection of Claims 1, 5-6, 10, 15-20, 25, 29, 31 and 33-36 under 35 USC § 102(b) and under 35 USC § 103(a)

The foregoing claims are rejected under 35 USC §§ 102(b) and 103(a) over the disclosure of U.S. Patent No. 5,447,688 (hereinafter "Moore") for the reasons noted at pages 7-10 of the Office Action. Applicants respectfully traverse these rejections for the reasons noted below.

Applicants' foregoing comments regarding the Puri and Stenholm references with regard to the "shrink-wrapped" feature and/or the "shrink-wrapping" step are applicable to the Moore reference. As with the Puri and Stenholm references, the Moore reference also fails to disclose, teach or suggest the "shrink-wrapped" feature or the "shrink-wrapping" step. Thus, for the same or similar reasons that Puri and/or Stenholm do not anticipate or do not render obvious Applicants' rejected claims, the Moore reference also fails to anticipate or fails to render obvious the above-noted claims. Applicants' prior comments regarding the deficiencies of the Puri and Stenholm references (to the extent applicable to the "shrink-wrapped" feature or the "shrink-wrapping" step) are equally relevant and are applicable deficiencies of the Moore reference. As such, those prior comments and remarks are incorporated herein without having to repeat the same.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the rejection of the above-noted claims under 35 USC §§ 102(b) and 103(a) over the disclosure of the Moore reference.

Rejection of Claims 14 and 32 under 35 USC § 103(a) over Puri

The above-noted claims are rejected as being obvious under 35 USC § 103(a) over the disclosure of Puri for the reasons noted at pages 10-11 of the Office Action. Applicants respectfully traverse this rejection for the reasons noted below.

Applicants' foregoing comments regarding the deficiencies of the Puri reference with regard to the "shrink-wrapped" feature and/or the "shrink-wrapping" step are equally applicable to the instant rejection of claims 14 and 32 under 35 USC § 103(a). Those prior comments and remarks are incorporated herein without having to repeat the same.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the foregoing claims under 35 USC § 103(a) over the disclosure of the Puri reference.

Rejection of Claims 1, 6, 10, 15-20, 25, 29, 31 and 33-36 under 35 USC § 103(a)

The foregoing claims are rejected under 35 USC § 103(a) as being obvious over the disclosure of U.S. Patent No. 5,322,797 (hereinafter "Mallow") in view of Puri or Stenholm for the reasons noted at pages 12-13 of the Office Action. Applicants respectfully traverse this rejection for the reasons noted below.

The Office Action asserts that the Mallow reference does not teach the specific composition of the film material, but that the Puri or Stenholm references do. See Office Action at page 13, lines 3-4 stating (in relevant part):

> Mallow et al. do not disclose the specific composition of the film material. Puri et al. and Stenholm disclose shrink-wrapped materials as recited above. [(Emphasis added.)]

Applicants strongly disagree with the above-noted assertion. Applicants' prior comments and remarks regarding the deficiencies of the Puri and Stenholm references are incorporated herein without having to repeat the same here. In particular, neither the Puri reference nor the Stenholm reference discloses the "shrink-wrapped" feature or the "shrink-wrapping" step recited in Applicants' rejected claims.

Likewise, the Mallow reference does not disclose those same features that the Puri reference and the Stenholm reference fail to disclose, teach or suggest. Specifically, no "shrink-wrapped" feature or "shrink-wrapping" step is disclosed in the Mallow reference. Accordingly, the combination of the Mallow reference with the Puri and/or the Stenholm references does not rectify the deficiencies of the Mallow reference.

Accordingly, the Mallow reference in view of the Puri reference or the Stenholm reference does not render obvious the above-noted claims rejected under 35 USC § 103(a). In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 6, 10, 15-20, 25, 29, 31 and 33-36 under 35 USC § 103(a) as being obvious over Mallow in view of Puri or Stenholm.

Rejection of Claims 1, 6, 8, 10, 15-20, 25, 27, 29, 31 and 33-36 under 35 USC § 103(a)

The foregoing claims are rejected under 35 USC § 103(a) as being obvious over U.S. Patent No. 4,106,428 (hereinafter "Matthiessen") in view of Puri or Stenholm for the reasons noted at pages 13-15 of the Office Action. Applicants respectfully traverse this rejection for the reasons noted below.

In particular, the Office Action asserts that the Matthiessen reference does not teach the specific composition of the chemically sensitive material, but that the Puri or Stenholm references do. See Office Action at page 15, lines 3-5 stating (in relevant part):

> Matthiessen does not disclose the specific composition of the chemically relevant material. Puri et al. and Stenholm disclose shrink-wrapped materials as recited above. [(Emphasis added.)]

Applicants strongly disagree with the above-noted assertion. Applicants' prior comments and remarks regarding the deficiencies of the Puri and Stenholm references are incorporated herein without having to repeat the same here. In particular, neither the Puri reference nor the Stenholm reference discloses the "shrink-wrapped" feature or the "shrink-wrapping" step recited in Applicants' rejected claims.

Likewise, the Matthiessen reference does not disclose those same features that the Puri reference and the Stenholm reference fail to disclose, teach or suggest. Specifically, no "shrink-wrapped" feature or "shrink-wrapping" step is disclosed in the Matthiessen reference. In fact, as opposed to being "shrink-wrapped," the "liner strips [of Matthiessen] are loosely slidable relative to the body" as noted in the Abstract of Matthiessen at lines 6-7 thereof.

Accordingly, the combination of the Matthiessen reference with the Puri and/or the Stenholm references does not rectify the deficiencies of the Matthiessen reference.

Therefore, the Matthiessen reference in view of the Puri reference or the Stenholm reference does not render obvious the above-noted claims rejected under 35 USC § 103(a). In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 6, 8, 10, 15-20, 25, 27, 29, 31 and 33-36 under 35 USC § 103(a) as being obvious over Matthiessen in view of Puri or Stenholm.

Rejection of Claims 2 and 21 under 35 USC § 103(a)

The above-noted claims (i.e., 2 and 21) are rejected under 35 USC § 103(a) as being obvious over Puri, Stenholm, or Moore further in view of U.S. Patent No. 4,958,895 (hereinafter "Wells") for the reasons noted at page 16 of the Office Action. Applicants respectfully traverse this rejection.

Namely, the above-noted comments and remarks regarding deficiencies of the Puri, Stenholm and Moore references are equally applicable here. Thus, those comments and remarks are incorporated herein without having to repeat the same here. Particularly, none of the Puri, Stenholm or Moore references disclose, teach or suggest the "shrink-wrapped" feature or the "shrink-wrapping" step expressly recited in Applicants rejected claims. Also, those aspects of Applicants' rejected claims are not disclosed, taught or suggested by the Wells reference.

In fact, Wells is non-analogous art directed to "Optical Waveguides" as its title implies. Thus, not only is Wells non-analogous art with respect to Applicants' rejected claims, but Wells does not rectify the deficiencies of Puri, Stenholm or Moore.

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of the foregoing claims under 35 USC § 103(a) as being unpatentable over Puri, Stenholm or Moore further in view of Wells.

Rejection of Claims 9 and 28 under 35 USC § 103(a)

The above-noted claims are rejected under 35 USC § 103(a) as being obvious over Puri, Stenholm or Moore further in view of U.S. Patent No. 5,352,517 (hereinafter "Clough") for the reasons noted at pages 16-17 of the Office Action. Note that Applicants find that U.S. Patent No. 5,352,517 corresponds to "Clough" and not to "DeGuire" – as recited at page 16, paragraph 13, line 15 of the Office Action. If the Office Action intended to recite a different U.S. patent number, then the Examiner is respectfully requested to supply the correct U.S. patent number and to re-open prosecution to give Applicants a full opportunity to address the correct rejection on its merits. Nevertheless, Applicants have addressed the rejection as they understand the Office Action to have been made over Puri, Stenholm or Moore further in view of Clough – which corresponds to the recited U.S. Pat. No. 5,352,517. Applicants respectfully traverse this rejection for the reasons noted below.

Particularly, the above-noted comments and remarks regarding deficiencies of the Puri, Stenholm and Moore references are equally applicable here. Thus, those comments and remarks are incorporated herein without having to repeat the same here. None of the Puri, Stenholm or Moore references disclose, teach or suggest the "shrink-wrapped" feature or the "shrink-wrapping" step expressly recited in Applicants rejected claims. Also, those aspects of Applicants' rejected claims are not disclosed, taught or suggested by the Clough reference.

In fact, Clough is non-analogous art directed to "Iron Oxide Coated Substrates" as its title implies and its Abstract indicates – "[p]rocess for coating substrates, in particular substrates including shielded surfaces, with iron oxide-containing coatings . . . for use in various magnetic

applications." Thus, not only is Clough non-analogous art with respect to Applicants' rejected claims, but Clough does not rectify the deficiencies of Puri, Stenholm or Moore.

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of the above-noted claims under 35 USC § 103(a) as being unpatentable over Puri, Stenholm or Moore further in view of Clough.

CONCLUSION

Based on the foregoing, all of Applicants' now-pending claims 1-36 are patentably distinguished over the cited art, and in form and condition for allowance. Favorable action is requested.

If any issues remain outstanding, incident to the allowance of the application, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss their resolution, in order that this application may be passed to issue at an early date.

Respectfully submitted,

Date: June 27, 2006

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